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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/542,390

07/13/2005

Dieter Manstein

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DORSEY & WHITNEY LLP  
INTELLECTUAL PROPERTY DEPARTMENT  
250 PARK AVENUE  
NEW YORK, NY 10177

EXAMINER

SHAY, DAVID M

ART UNIT

PAPER NUMBER

3769

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/542,390	<b>Applicant(s)</b> MANSTEIN ET AL.	
	<b>Examiner</b> david shay	<b>Art Unit</b> 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on April 7, 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 63-93,95-109 and 113-139 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 63-93, 95-109, and 113-139 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>April 7, 2009</u> .   | 6) <input type="checkbox"/> Other: _____                          |

Applicant has submitted new drawing sheets which purport to comply with the examiners objections. However, with respect to e.g. Figure 5, the numeral “402” is not universally recognized as a “shielding structure”, similarly, the numeral “502” is not universally recognized as a “microchannel” thus the submitted drawing corrections are insufficient to remedy the problems with the original drawings.

The drawings are objected to because in Figure 4, elements 400 and 402 are not labeled with indicia indicative of their function; in Figure 5, elements 402 and 502 are not labeled with indicia indicative of their function; in Figure 6, elements 402 and 602 are not labeled with indicia indicative of their function; in Figures 7A and 7B, element 709 is not labeled with indicia indicative of its function; in Figure 8, elements 716 and 800 are not labeled with indicia indicative of their function; and in Figure 9, elements 906 is not labeled with indicia indicative of its function. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

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the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “the target area has an areas of about one square centimeter”; the “at least one hundred of the particular areas”; and the “at least one thousand of the particular areas” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are

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canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 88 (second occurrence) been renumbered 89.

The amendment filed March 27, 2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the damage “from a surface of the skin through an entire depth of the epidermal tissue” while cooling the tissue.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 70, 71, 80, 81, 100, 101, 120, 121, 130, and 131 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure is silent on the damage be “from a surface of the skin through an entire depth of the epidermal tissue” while the tissue is cooled.

Claims 64, 74, 88, 89, 91, 108, 109, 114, 138, and 139 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 64 and 114, are indefinite as they fail to further limit the claims from which they depend, and therefore what further limitation is intended to be implied is unclear, as claims 63 and 113 require that the damage be “from a surface of the skin through an entire depth of the epidermal tissue” the only laser disclosed in the originally filed disclosure that does this is an ablative laser. In claim 74 it is unclear what further structure is intended to be implied by reciting the effect of the radiation on the skin. In claims 88, 89, 91, 108, 109, 138, and 139, exactly what range of areas is intended to be encompassed by “about one square centimeter” is unclear as this recitation lacks positive antecedent basis in the originally filed disclosure.

Claims 63-70, 72-80, 82-87, 90-93, 95-100, 102-107, 113-120, 122, 123, 125-130, and 132-137 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Debenedictis et al (WO 2003/0216719).

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See Figures 1-7 and paragraphs [0011]-[0013], [0024]-[0035], [0040], [0044]-[0050], and [0053]-[0061].

Claims 63-93, 95-109, and 113-139 are rejected under 35 U.S.C. 103(a) as being unpatentable over Debenedictis et al (WO 2003/0216719) in combination with Altshuler et al (WO 2002/053050) and Altshuler et al (US 6,517,532). Debenedictis et al (WO 2003/0216719) teaches a device and method such as claimed except the particular temperature to which the tissue is cooled; the treatment area size and the number of spots in the area; Altshuler et al (WO 2002/053050) teach a device and method as claimed, except the particular structure of the applicator with the transparent plate; the temperature to which the plate is cooled; the damaging of the surface of the epithelium, and that the controller, laser, and the delivery arrangement are all in the same housing. Altshuler et al (US 6,517,532) teaches an applicator with a cooled plate as claimed. It would have been obvious to the artisan of ordinary skill to employ a device and method as taught by Altshuler et al (US 6,517,532) in the device and method of Altshuler et al (WO 2002/053050) or Debenedictis et al (WO 2003/0216719), since Altshuler et al (WO 2002/053050) and Debenedictis et al (WO 2003/0216719) provide no particular structure and with regard to the cooling portion of the applicator, and to place all the components in a single housing, since this is not critical; is well within the skill of one having ordinary skill in the art; provides no unexpected result; and would render the device more easily movable from one place to another, and to configure the device to damage the surface of the epithelium, since this is a known technique for skin resurfacing, as taught by Debenedictis et al (WO 2003/0216719), and in either case, to provide the treatment area and number of treatment zones claimed, since this is not critical; is well within the skill of one having ordinary skill in the art; and provides no

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unexpected result, and to cool the skin to at least 37 degrees Celcius and at most negative 20 degrees Celcius, since this is not critical; is well within the skill of one having ordinary skill in the art; provides no unexpected result; and would prevent undesired damage to adjacent tissue,thus producing a device and method such as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson, can be reached on Monday through Friday from 7:00 a.m. to 3:30 p.m. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/david shay/  
Primary Examiner, Art Unit 3769